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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,095	10/31/2003	William J. Bertrand	P-11490.00	1017

7590 04/18/2007

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,095	BERTRAND ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 18-30* is/are rejected.

7)☒ Claim(s) *2,17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated January 8, 2007. Claims 1-3, 6, 8-11, 13-14, 16-17, 21-25 and 30 are amended. Claims 1-30 are pending.

Drawings

The drawings for Figures 1, 2 and 9 were received on January 8, 2007. These drawings are acceptable.

In view of Applicant's amendments to the drawings the drawing rejections for Figures 1, 2 and 9 are withdrawn. However, the following applies for Figure 8 as set forth in the Office Action dated October 5, 2006.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (800) as seen in Figure 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective

action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

In view of Applicant's amendments to the claims dated January 8, 2007, the claim objections set forth in the Office Action dated October 5, 2006 are withdrawn

Claim Rejections - 35 USC § 112

In view of Applicant's amendments to the claims dated January 8, 2007, the claim rejections under 35 USC 112, second paragraph set forth in the Office Action dated October 5, 2006 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-11, 13-14, 16, 18-21, 24, 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (US 2002/0022793 A1) in view of Haynor et al. (US 6216028 B1).

Bertrand et al. teaches a magnetic based indicator tool comprising: a housing having a display (28), at least one magnetic field sensor (62) to determine a spatial location and orientation of a magnetic indicator device (20) (as described in paragraphs [0010] and [0066]) associated with a valve (10) of an implantable flow control device (as described in paragraphs [0010], [0062]-[0066]), a processing module (88) that receives

information from said magnetic field sensor (62) and determines a setting for the valve (10) (as described in paragraphs [0052]-[0058]) on the implantable flow control device using the determined orientation of the magnetic indicator device (20), further comprising a magnetic adjustment tool (30) that modified an orientation of the valve (10) in the implantable flow control device (as described in paragraphs [0062]-[0066]), said magnetic adjustment tool comprising a magnetic adjustment component (90) that magnetically couples to the magnetic indicator device (20) of said flow control device, wherein rotating said adjustment tool while said magnetic adjustment component (90) is magnetically coupled to said magnetic indicator device (20) of said flow control device causes said valve (10) of said flow control device to rotate, thus changing the setting of said valve (10). While Bertrand et al. teaches that said housing has a display, an electronic display is not expressly taught. Furthermore, Bertrand et al. does not teach the use of a plurality of magnetic sensors grouped into sets or that said magnetic sensor determines a value for ambient magnetic fields or a removable storage device.

Haynor et al. teaches an electronic magnetic-based indicator tool and method of using the tool comprising a housing having an electronic display; a plurality of magnetic field sensors grouped into sets; and a processing module for receiving magnetic data values from the plurality of magnetic field sensors making it capable of determining a setting for a valve on an implantable flow control device wherein the plurality of magnetic field sensors may comprise four sets of three sensors (as described in lines 2-10 and lines 23-28 of the abstract; in lines 52-59 of column 2; and in claim 35); wherein the indicator tool is positioned over an estimated location of the implanted magnetic device; wherein the magnetic field sensors may be Hall-effect sensors (as described in

lines 26-29 of column 3) for determining location and orientation of a magnetic device for the x, y and z axis and for theta and fie (as described in lines 53-60 of column 5; in lines 56-58 of column 6; in lines 6-10 and 14-28 of column 7), therefore the orientation is determined in five degrees of freedom; wherein the processing module determines an estimate for ambient magnetic fields from a sequence of magnetic data values and subtracts the estimate from received magnetic data values to determine the location and orientation of only the field of the implanted magnetic device (as described in lines 40-45 and 54-57 of column 3; and in lines 57-60 of column 4); wherein the user operated tool further comprises a removable data storage device (170) containing computer readable data capable of being used to translate a valve setting into pressure for an implantable flow control device (as seen in Figures 5A-B).

It would have been obvious to one having ordinary skill in the art at the time of the invention use an electronic magnetic indicator tool similar to that of Haynor et al. with a control system as taught by Bertrand et al. in order to sense and display valve settings of an implantable flow control device similar to that of Bertrand et al. as an improvement because indicators devices comprising a compass relies upon the torque generated by the magnetic forces between a nearby magnet (such as one on an implantable device) and the magnetized compass pointer in order to point the compass towards said nearby magnet which usually results in inaccurate orientation (as described in lines 16-30 of column 2of Haynor et al.). It would have been inherently obvious to one having ordinary skill in the art at the time of the invention that the electronic controls of the combination of Bertrand et al. and Haynor et al. would

comprise an ON/OFF feature that would allow a user to activate said tool using a power supply (as described in lines 2-5 of column 22 of Haynor et al.).

Claims 12 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bertrand et al. (US 2002/0022793 A1) and Haynor et al. (US 6216028 B1) as applied to claims 11 and 21 above, in view of Drinan et al. (PGPUB 2003/0004403 A1).

The combination of Bertrand et al. and Haynor et al. teaches the electronic magnetic-based indicator tool of claims 11 and 21, as described above, comprising a computer having an internal memory and the use of a recorder to save the images created from the output data on the visual display but does not teach the use of a removable data storage consisting of flash memory or a compact flash memory device.

Drinan et al. teaches a tool for remote monitoring of an implant within a human body comprising a handheld detector and a computer (as described by the abstract and as seen in Figures 1-2), wherein flash memory and a compact flash memory device are used to store data from said detector and said computer (as described in claims 1, 33 and 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to save the sensed and processed data from a tool similar to that of the combination of Bertrand et al. and Haynor et al. using flash memory or a compact flash memory device similar to that taught by Drinan et al. because this is an affordable and easy way to transport the medical data between different doctor's computers and a way to create an archive other than the information saved on the computer. It would have been inherently obvious to one having ordinary skill in the art at the time of the invention

that all information taken, used and saved from a patient's implant would correspond to that particular patient and that particular implant within said patient.

Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bertrand et al. (US 2002/0022793 A1) and Haynor et al. (US 6216028 B1) as applied to claims 14 and 24 above, in view of Penner et al. (US 2002/0077673 A1).

The combination of Bertrand et al. and Haynor et al. teaches the electronic magnetic-based indicator tool of claims 14 and 24, as described above, wherein in one embodiment the tool is a handheld device containing the magnetic sensors and associated electronics which require power (as described in lines 2-5 of column 22 of Haynor et al.). However, this combination does not expressly teach the use of batteries as a power supply.

Penner et al. teaches the use of a handheld device comprising batteries to power the electronics used to communicate and interact with a device implanted within a patient (as described in paragraph [0059]), wherein said implant may be a valve and wherein said handheld device may be a controller used to open or close said valve (as described in paragraph [0033]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use batteries as a portable power supply similar to that of the device of Penner et al. with a device similar to that of the combination of Bertrand et al. and Haynor et al. in order to enhance the portability of said device, compared to alternative power supplies which involve cables, wires and/or generators.

Allowable Subject Matter

Claims 2 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 2 and 17, none of the prior at of record teaches or fairly suggests a system comprising an implantable medical device comprising a magnetic indicator device associated with a valve of an implantable flow control device, an electronic magnetic based indicator tool comprising a housing, an electronic display and a plurality of magnetic fiend sensors grouped into sets of three, a processing module that receives magnetic data values from the plurality of magnetic field sensors and determines a setting for said valve and an adjustment tool that modifies the orientation of said valve, wherein said processing module determines the setting of said valve on the implantable flow control device using a determined orientation of a reference magnet coupled to said implantable flow control device at a location separate from said magnetic indicator device.

Response to Arguments

Applicant's arguments dated January 8, 2007, with respect to the rejection of claims 1-3 under 35 USC 102(b) as anticipated by Golden et al. and to the rejection of claims 1, 4-7, 11, 13-14 and 26-30 under 35 USC 102(b) as anticipated by Haynor et al. have been fully considered and are persuasive in view of Applicant's amendment to include the limitation "associated with a valve of an implantable flow control device". The rejection under 35 USC 102 of the above noted claims has been withdrawn.

Applicant's arguments with respect to the rejection(s) of claim(s) under 35 USC 103 set forth in the Office Action dated October 5, 2006 have been fully considered and are persuasive in view of Applicant's amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bertrand et al. Haynor et al., Drinan and Penner et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hooven (US 4676772 A) teaches an adjustable implantable valve having non-invasive position indication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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S.L.

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